

Remarks

Claims 1-5 and 10-27 were pending in this application. Claim 20 has been canceled. Claims 1, 5, 14, 22, 24, and 25 have been amended. No new matter is introduced by these amendments. Applicants reserve the right to pursue protection for any subject matter removed from the claims by this amendment. After entry of this amendment **claims 1-5, 10-19, and 21-27 are pending in this application.**

Claim Rejections under 35 U.S.C. §112, second paragraph:

Claims 1-4 and 22 have been rejected under 35 U.S.C. §112, second paragraph because allegedly essential steps are omitted from independent claims 1 and 22.

35 U.S.C. § 112, second paragraph, is the statutory basis for a notice function, which requires applicant to “provid[e] clear warning to others as to what constitutes infringement” (MPEP §2173.02 citing, *e.g.*, *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000)). If a claim “apprises one of ordinary skill in the art of its scope,” then its language is not indefinite (MPEP §2173.02). As stated by MPEP 2173.04: “If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.” Applicants therefore believe that the claims do not require amendment.

However, in order to advance prosecution in this matter, independent claims 1 and 22 have been amended to include “selecting a subject in need of vasoconstriction” (claim 1) or “selecting a subject in need of vasodilation” (claim 22), and to add the conclusion “thereby vasoconstricting blood vessels in the subject” (claim 1) or “thereby vasodilating blood vessels in the subject.” (claim 22). No “detection” steps are required to carry out the claimed methods, and the scope of the subject matter embraced by claims 1 and 22 is clear.

Based on the foregoing arguments and amendments, Applicants request that the rejection of claims 1-4 and 22 under 35 U.S.C. §112, second paragraph be withdrawn.

Claims 5, 10-21, and 25-27 have been rejected under 35 U.S.C. §112, second paragraph because the claims as written allegedly are ambiguous because it is unclear whether the peptide AM(11-22) is that of SEQ ID NO: 4. Though Applicants believe the claims as written were clear

with regard to the peptide, claims 5, 14, and 25 have been amended herewith to include the sequence identifier "SEQ ID NO: 4." Claims 10-13, 15-21, and 26-27 depend from independent claims 5, 14, and 25. Therefore, claims 5, 10-21, and 25-27 are not indefinite, and comply with 35 U.S.C. 112, second paragraph.

Based on the foregoing amendments, Applicants request that the rejection of claims 5, 10-21, and 25-27 under 35 U.S.C. §112, second paragraph be withdrawn.

Claim 14 has been rejected under 35 U.S.C. §112, second paragraph because the claim is allegedly ambiguous because there are not steps for the screening method. Though Applicants believe the claims as written were clear with regard to the peptide, claim 14 has been amended to include "selecting a compound," and to conclude with "thereby screening for the inhibitor of AM(11-22)." No additional steps are required to carry out the claimed method, and the scope of the subject matter embraced by claim 14 is clear. Therefore, claim 14 is not indefinite, and it complies with 35 U.S.C. 112, second paragraph.

Based on the foregoing amendments, Applicants request that the rejection of claim 14 under 35 U.S.C. §112, second paragraph be withdrawn.

Claims 20 and 24 have been rejected under 35 U.S.C. §112, second paragraph because the term "small" allegedly is ambiguous. While Applicants believe the scope of the term "small molecule inhibitor" would be recognized by one of ordinary skill in the art, Applicants have canceled claim 20 and amended claim 24 to delete the term "small molecule inhibitor" in order to advance prosecution in this matter. Based on the foregoing amendment, Applicants request that the rejection of claim 24 under 35 U.S.C. §112, second paragraph be withdrawn.

Claim Rejections under 35 U.S.C. §103:

Claims 1, 5, 10, 13-18, 21-25, and 27 have been rejected under 35 U.S.C. §103(a) as allegedly being obvious in light of Kitamura *et al.* Applicants traverse this rejection.

To establish a *prima facie* case of obviousness, the Examiner must identify all of the claimed elements in one or more prior art references (MPEP §2143). Kitamura *et al.* does not disclose AM(11-22), but rather discloses a vasoactive peptide (AM(11-26)) that is 33% longer than AM(11-22), and that also differs at position 19. No other references are cited. Because the reference cited by the Examiner fails to teach or suggest all of the elements of the claims, it cannot serve as the basis of a rejection of the claims under 35 U.S.C. §103(a), particularly when

cited alone. Thus, Applicants request that this rejection of 1, 5, 10, 13-18, 21-25, and 27 be withdrawn.

In addition, Applicants note the activity of claimed peptide AM(11-22) is unexpectedly superior to that of the peptide disclosed in Kitamura *et al.* Page 13, lines 13-14 of the specification states that AM(11-22) “surprisingly exhibits an unusually long duration of activity (on the order of hours) in comparison to previously known AM-derived peptides.” In addition, Figure 4 of the present application shows the first several minutes of the sustained elevation in blood pressure that results from administration of AM(11-22). By contrast, Figure 4 of Kitamura *et al.* demonstrates that the elevation in blood pressure resulting from administration of AM(11-26) lasts only about 70 seconds.

The prolonged kinetics of activity of the AM(11-22) peptide could not have been predicted from its amino acid sequence, nor from a mere comparison to previously described AM peptides. This particularly long activity duration of AM(11-22) makes it superior to prior AM-related peptides, and contributes to the usefulness of AM(11-22) as an antihypotensive agent. One of skill in the art will understand that an antihypotensive agent with a duration of action on the order of hours is far more clinically useful than an agent with a duration of action on the order of seconds, and this distinction renders AM(11-22) unexpectedly superior as a vasoconstrictive or antihypostensive agent.

Based on all of the foregoing arguments, Applicants request that the rejection of claims 1, 5, 10, 13-18, 21-25, and 27 under 35 U.S.C. §103(a) be withdrawn.

Conclusion


It is respectfully submitted that the present claims are in a condition for allowance. If any issues remain, the Examiner is requested to contact the undersigned attorney prior to issuance of the next Office action in order to arrange a telephone interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution and allowance of the claims.

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